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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/424,247	10/30/2002	Francis Vanderbist	4068-0002-0P	7736

22429 7590 10/07/2005

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EXAMINER

BERKO, RETFORD O

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 10/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/424,247	VANDERBIST ET AL.	
	Examiner	Art Unit	
	Retford Berko	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Acknowledgement: Applicant's Request For Continued Examination (RCE) filed 7/14/05 is acknowledged.

Status of Claims

The status of the claims is as follows:

Claims 1-38 are cancelled.

Claims 39-53 are pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 38-38 are rejected under 35 U.S.C.103(a) as being unpatentable over Sarlikiotis et al (US 6, 284, 287) in view of the combination of Stevenson et al (US 4, 199, 578), and Cutie et al (US 5, 891, 419).

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Sarlikiotis et al (Patent '287) disclosed a powder formulation filled into an inhaler (col 3, lin 10; col 6, lin 3 and col 7, lin 1-5); said composition having particle size of 400-1000 microns and rugosity more than 1.75 (col 7, lin 10) and wherein the active agent is present at 30%-70% and the excipient is present in the mixture in a specified amount (col 8, lin 5-10). According to Sarlikiotis et al, the formulation contains active agents e.g. steroids, budesonide, salbutamol and disodium cromoglycate and excipients (e.g. lactose, maltose and cyclodextrin)---col 3, lin 25-50, col 4, lin 5-10 and col 5, lin 60-65, continuing to col 6, lin 30-60; col 4, lin 13, col 5, lin 65 and col 6, lin 11). Further, Sarlikiotis et al disclosed the process of making the composition (i.e. claims 20 and 31-38).

Sarlikiotis et al (Patent '287) does not teach the use of beta-lactose as excipients in the formulation.

Stevenson (Patent '578) disclosed powdered composition for treatment of asthma (abstract), acceptable for inhalation (col 3, lin 1 and col 5, lin 10-15) comprising crystalline lactose (col 3, lin 10, col 4, lin 22) and drug (col 4, Examples 1 and 2) that is of particle size of below 400 microns, acceptable in the nose or lung (col 5, lin 20-25).

Cutie et al (Patent '419) disclosed aerosol formulations for inhalation comprising drug and beta lactose as excipient (abstract, col 3, lin 33, col 10, lin 35-40. The reference is relied upon for the disclosure of solving the same problem in the art of inhalation compositions for treatment and the use of excipients—specifically beta lactose. According to Cutie, beta lactose is a preferred excipient because it is useful as a dispersing agent, stability modifier, density modifier, drug transport facilitator and carrier of additives and respiratory sensitizer or desensitizer.

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One of ordinary skill in the art would have been motivated to prepare particulate formulations comprising active ingredients and excipients for inhalation for treatment of respiratory diseases such as asthma as disclosed in the prior art cited. By using the combination of methods disclosed in the prior art cited, one of ordinary skill would expect reasonable level of success in obtaining a composition having the necessary effective drugs and physical characteristics such as particle size rugosity; such physical characteristics permitting the composition to be beneficial in improving mucus rheological properties and thereby increase the efficiency of removing accumulated secretions from the lung airways for asthma patients and patients with other respiratory ailments. Therefore the invention as a whole would have been prima facie obvious to one of ordinary skill at the time it was made.

The following prior art references are cited for the record as pertinent to applicant's claims but are not relied upon in for making the rejections in this office action:

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Retford Berko** whose telephone number is 571-272-0590. The examiner can normally be reached on M-F from 8.00 am to 5.30 pm

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Thurman K Page**, can be reached on 571-272-0602.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600